In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 18-586V

(not to be published)

* *	Special Master Corcoran
OKSANA MOTUZYUK, *on behalf of* A.R.K., *	
*	Filed: February 14, 2019
Petitioner, *	
v. *	Dismissal; Autism Spectrum Disorder; Encephalopathy; Table Claim.
*	
SECRETARY OF HEALTH AND HUMAN SERVICES, *	
*	
Respondent. *	
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* *	

Yuri Jelokov, Farrish Johnson Law Office, Mankato, MN, for Petitioner.

Voris E. Johnson, U.S. Dep't of Justice, Washington, DC, for Respondent.

DECISION DISMISSING PETITION[1]

On April 25, 2018, Oksana Motuzyuk, on behalf of her minor son, A.R.K., filed a Petition under the National Vaccine Injury Compensation Program (the "Vaccine Program").[2] The Petition alleges that a Pentacel vaccine (containing the diphtheria-tetanus-acellular pertussis ("DTaP"), inactivated polio ("IPV"), and haemophilus influenzae type b ("Hib") vaccines) A.R.K. received on April 29, 2015, caused him to suffer an Autism Spectrum Disorder ("ASD").

A few months after the Petition's filing, I held a status conference with the parties. At that

[1] Although I am not formally designating this Decision for publication, it will nevertheless be posted on the Court of Federal Claims's website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means the Decision will be available to anyone with access to the internet**. As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the Decision will be available to the public in its current form. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended, 42 U.S.C. §§ 300aa-10 through 34 (2012) [hereinafter "Vaccine Act" or "the Act"]. Individual section references hereafter will be to § 300aa of the Act.

time, I explained to Petitioner that her case appeared indistinguishable from countless prior claims alleging a vaccine administered to a child caused an ASD—and that such claims had never found success. *See* Order at 1, dated July 6, 2018 (ECF No. 7) (citations omitted). I therefore invited Respondent to request the claim's dismissal with the filing of his Rule 4(c) Report. *Id.* at 2. Respondent did so on November 13, 2018. *See generally* Motion to Dismiss (ECF No. 12) and Resp't's Rule 4(c) Report in Support of his Motion to Dismiss (ECF No. 13) (collectively, "Mot."). Petitioner filed her opposition to such relief on December 7, 2018. *See generally* Pet'r's Objection to Resp't's Mot. to Dismiss (ECF No. 14) ("Opp."). Having now had the opportunity to review these filings in light of the medical record, I find that Respondent's motion is well-founded, and (for the reasons stated below) dismiss Petitioner's claim.

Brief Summary of Relevant Medical Records

A.R.K. was born via vaginal delivery on February 10, 2014, in Chicago, Illinois. Ex. 14 at 74. His birth weight was 8 pounds, 10.8 ounces, and he initially required suctioning, oxygen and tactile stimulation due to having respiratory distress and poor muscle tone. Ex. 15 at 11–12. A newborn screening was normal, however. *Id*. at 6–7.

There is a subsequent gap of almost one year in the medical records filed to date in this case (an omission not attributable to a lack of diligence on Petitioner's part, but rather to difficulties getting certain treaters to disclose records). The earliest record after A.R.K.'s birth details his eleven-month well-child exam on January 24, 2015, with Lubov A. Klemine, M.D., in Chicago. Ex. 2 at 1–2. No developmental concerns were noted, and on exam A.R.K. had good eye contact and responded appropriately. *Id.* The following month, Dr. Klemine again saw A.R.K. for a well-child exam on February 28th. *Id.* at 3–4. The developmental assessment and physical exam on this visit were identical to the previous visit, and the record indicates that A.R.K. still had good eye contact and responded appropriately. *Id.*

Two months later, on April 29, 2015, A.R.K. saw Dr. Klemine for his fourteen-month well-child exam. Ex. 2 at 6. His weight, height, and head circumference were all on the upper end of the growth chart at this visit, and his parents expressed no concerns about his development, which was reportedly normal. *Id.* At this time A.R.K. received the Pentacel vaccine at issue in this case. *Id*. at 7.

No medical records exist memorializing an immediate reaction to this vaccination. Petitioner, however, maintains that later the same day, A.R.K. developed a high fever and displayed several other indicia of severe distress (e.g., sweating, convulsing, inconsolably crying). Ex. 12 at ¶ 14. Petitioner allegedly called Dr. Klemine that evening (although no record memorializing this call has been filed), who told her that A.R.K.'s condition should resolve soon, but that she should take him to the emergency room if it worsened. *Id*. at ¶ 15. By the next day, A.R.K. was allegedly a "different person," and he became increasingly unresponsive, detached, and weak as the days progressed. *Id*. at ¶ 17.

Approximately one week later, on May 7, 2015, A.R.K. was seen by Amy L. Whalen, M.D., in the Lurie Children's Hospital emergency department ("ED") in Chicago. Ex. 17 at 21. Ms. Motuzyuk reported that A.R.K. had received vaccinations the previous Wednesday, and (consistent with the statements she has made in conjunction with the Petition's filing) that he had a fever for two days after his vaccinations, but it had resolved. *Id*. A.R.K. reportedly had also experienced vomiting with the fever, but none since, although he had some non-bloody diarrhea for a couple of days. *Id*. Now, however, A.R.K. was not responding to his name, having trouble making eye contact, and sleeping more. *Id*. The ED record does not specify, however, *when* any of these behavioral symptoms actually began.

Dr. Whalen's exam revealed that A.R.K. had good eye contact and turned toward a dropped toy and toward a medical student. Ex. 17 at 23. The assessment stated that A.R.K. had a resolved fever, vomiting, and diarrhea after a vaccine, which may have been a typical vaccine reaction, although the vomiting and diarrhea made Dr. Whalen "suspect [a] viral illness as well." *Id*. Dr. Whalen also assessed A.R.K. with speech delay with questionable eye contact and interest in interacting with people. *Id*. She noted that while A.R.K. was not clearly autistic based on the limited ED exam, ASD concerns should be addressed through a complete early intervention assessment in an appropriate setting. *Id.* Dr. Whalen also "[d]iscussed the lack of evidence linking vaccines to autism." *Id.*

The next day (May 8, 2015), A.R.K. returned to the Lurie Children's Hospital ED and saw Dimple Damani, M.D. Ex. 17 at 38. Petitioner reported that A.R.K. was experiencing headache and also had failed to make good eye contact "since his vaccines 1 week ago." *Id*. His parents also thought he was having problems hearing them, and Dr. Damani noted that their pediatrician had given them an audiology referral. *Id*. During this evaluation, however, A.R.K. was responding to his father and playing, and also made eye contact with his parents and Dr. Damani. *Id*. at 37, 39. Dr. Damani assessed A.R.K. with speech delay, back rash (either heat-induced or viral), continuing diarrhea, resolved vomiting, and resolved fever (the last three of which she attributed to a likely viral illness). *Id*. at 39. In addition, Dr. Damani performed blood tests at the request of Petitioner and her husband. *Id.* The results were largely normal except for low carbon dioxide and elevated blood urea nitrogen.[3] *Id.* at 47–48. A.R.K. was given fluids and ibuprofen. *Id.* at 48–49.

Later that May, A.R.K. was seen by Rebecca Kyllonen, Au. D., for an audiology evaluation. Ex. 16 at 12. His parents reported that they were concerned about his hearing (he seemed to hear but did not always respond), and also raised questions about his speech and language development and his social abilities. *Id*. A.R.K. was allegedly babbling at around eight months of age, but his parents reported that his speech had since declined (which would situate onset of that decline as *prior* to the vaccination in question in this case). *Id*. A.R.K. had a normal

[3] Blood urea nitrogen is the concentration of urea ($CO(NH_2)_2$) in a patient's blood or serum expressed in terms of nitrogen content. *Dorland's Illustrated Medical Dictionary* 2005 (32nd ed. 2012).

audiology evaluation for optoacoustic emission responses in both ears, but behavioral responses could not be obtained. *Id*.; *see also* Ex. 5 at 1.

On May 21, 2015, A.R.K. had an MRI which produced normal results. Ex. 5 at 3. He also received an audiologic re-evaluation in early June which could not produce reliable results. Ex. 16 at 12. There were no findings to suggest hearing loss or other hearing concerns, and the recommendation was for a developmental evaluation. *Id*. at 13.

There is another lengthy gap in the records, with the next evidence of a treater visit from November 16, 2015, when A.R.K. was seen for an eighteen-month well-child visit by Mira Kuder, M.D., at U.K. Family Practice. Ex. 4 at 3. His physical exam was normal, and while the developmental screen is not documented in this particular record, the assessment was that A.R.K. officially had developmental delay. *Id*. But a prolonged EEG performed on December 3, 2015 (looking for clinical findings of speech delay and absence attacks) was normal and without epileptiform discharges. Ex. 17 at 59.

Petitioner has filed other records from 2016 and beyond which largely confirm A.R.K.'s ASD diagnosis, but also provide some additional evidence relevant to her vaccine injury claim. For example, A.R.K. was seen by pediatric neurologist Jennifer P. Rubin, M.D., on March 21, 2016, for evaluation of developmental delay. Ex. 17 at 98; *see also* Ex. 3 at 49. At this time Dr. Rubin assessed him with developmental delay, more affecting social interactions and receptive and expressive language, with possible regression around fifteen months of age (which would have been close in time to the vaccination at issue). *Id*. In addition, a second EEG performed on July 1, 2016, resulted in abnormal findings, with midline focal epileptiform discharges at the frontal central vertex while awake and sleeping, and bifrontal bursts of epileptiform discharges. Ex. 3 at 14. Later that September, Dr. Rubin saw A.R.K. again, assessing him with developmental delay, most notable for speech and social impairment consistent with ASD. Ex. 17 at 195. At this same visit, Dr. Rubin also noted that A.R.K. demonstrated no new signs or symptoms of regression since his March 2016 visit, and her notes from this visit do not otherwise confirm an overall trend of regression. Ex. 17 at 195 ("no regression").

By October 2016, certain treaters were more definitive in assessing A.R.K. as suffering from an ASD. *See, e.g.*, Ex. 17 at 201, 203 (social interaction, communication, and play skills assessed in the ASD range), 204–06 (developmental pediatrician proposing that A.R.K. met criteria for ASD). Subsequent records are consistent. In addition, another neurologist evaluated A.R.K. as recently as September 2018, and includes in the history section of the relevant record the statement that he had a "past medical history significant for purported regression following vaccination at 15 months," although the neurologist also provided Petitioner and her husband with literature indicating that vaccines did not increase the risk of autism. Ex. 18 at 5, 8.

ANALYSIS

To receive compensation under the Vaccine Program, a petitioner must prove either (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to a vaccine identified on the Table that the petitioner or injured party received, or (2) that he suffered an injury that was actually caused by a vaccine. *See* §§ 11(c)(1), 13(a)(1)(A).

Petitioner has not styled her claim as arising from the Vaccine Table. However, an examination of the record does not uncover any evidence that A.R.K. likely suffered an encephalopathy as defined by the Table after receipt of the DTaP vaccine[4] (which was included in the Pentacel vaccine A.R.K. received). *See* 42 C.F.R. § 100.3(a)(II)(B) (2018). To succeed generally on such a claim, a petitioner would not to establish *both* that the injured party experienced an "acute" encephalopathy—typically evidenced by a decreased change in consciousness (as that term is defined in the Qualifications and Aids to Interpretation, 42 C.F.R. § 100.3(c)(2) (2018)) of sufficient severity to warrant hospitalization—and that the encephalopathy subsequently became "chronic" (that is, it lasted for at least six months). *Thompson v. Sec'y of Health & Human Servs.*, No. 15-1498V, 2017 WL 2926614, at *7–8 (Fed. Cl. Spec. Mstr. May 16, 2017).

The medical records filed in this case do not establish that A.R.K. experienced an acute encephalopathy within seventy-two hours of his Pentacel vaccination, as he did not experience a significantly decreased level of consciousness. At most, he may have displayed some nascent ASD-like symptoms and may have displayed some immediate but ultimately transient reaction to the vaccines he had just received. He was also never deemed by treaters (whether the day after vaccination or even once he was taken to the ED in early May) to be sufficiently ill to warrant immediate hospitalization (despite his parents' reasoned concern for changes in his behavior that they began to observe—changes that led them to seek emergency care). Nor did A.R.K. subsequently experience a chronic encephalopathy. The evidence in the record from the six or more months after vaccination suggests normal MRI and EEG readings; the 2016 EEG reading that was abnormal is too temporally attenuated to be deemed vaccine-causal. The evidence of A.R.K.'s developmental symptoms manifesting in the months after vaccination cannot persuasively be pointed to as proof of "encephalopathy"—they are at most *sequelae* of an alleged encephalopathy, and therefore it is circular reasoning to propose that they prove A.R.K. also experienced an encephalopathy in the first place. *See R.V. v. Sec'y of Health & Human Servs.*, No. 08-504V, 2016 WL 3882519, at *34 n.80 (Fed. Cl. Spec. Mstr. Feb. 19, 2016), *aff'd*, 127 Fed. Cl. 136 (2016).

Petitioner's non-Table claim fares no better. To the extent Ms. Motuzyuk alleges that

[4] Encephalopathy following the IPV or Hib vaccine (the other two constituents of Pentacel) is not recognized as a Vaccine Table injury. *See generally* 42 C.F.R. § 100.3(a) (2018).

A.R.K. experienced symptoms in the hours and days following his vaccination, those symptoms were not consistent (either in nature or severity) with an encephalopathy. Drs. Whalen and Damani, the ED physicians, suspected that he was merely suffering from a viral illness based upon his presentation at that time. *See* Ex. 17 at 23, 39. Moreover, while some records in A.R.K.'s history note that he experienced a developmental regression following his April 29, 2015 Pentacel vaccination, other records fail to confirm an overall trend of regression. *See, e.g.*, *id.* at 195. The records supporting the contention that A.R.K. regressed significantly come a year or more after the relevant time period, while the most contemporaneous records do not clearly document any mental status changes within seventy-two hours of the vaccination. All that remains is the fact that (a) A.R.K. had an initial, if transient, reaction to the vaccine, and (b) Petitioner first noticed symptoms that were likely related to A.R.K.'s subsequently-diagnosed ASD thereafter. This is the classic temporal association between vaccination and injury that is recognized as insufficient to meet the preponderant standard for an entitlement award. *See McCarren v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 142, 147 (1997).

Give the above, I conclude that Petitioner will not be able to establish preponderant evidence in favor of her claim, and therefore the matter should not proceed, even if expert reports have not yet been obtained.[5] In so deciding, I am heavily, and reasonably, influenced by the many prior cases alleging autism as a vaccine injury that have been decided in the Vaccine Program. Because of the short timeframe between vaccination and discovery of A.R.K.'s first presenting ASD symptoms, in a case with a *different* causation theory and injury, the equities might support permitting the Petitioner to at least try to obtain an expert who could opine that the vaccines at issue likely caused the subsequent injury. But the question of the propensity of vaccines to cause *autism* has been largely foreclosed in the Vaccine Program by a host of extremely well-reasoned, carefully-considered cases decided over the past twelve years.[6] There is no justification in this

[5] Petitioner has submitted an expert letter opinion from a Ukrainian physician, Dr. Oksana Ivanivna Nikonova (Ex. 11 at 1), but that letter does not set forth any theory of causation. The opinion expressed therein mostly seems to endorse the view that A.R.K. has an ASD, but then conclusorily pivots to the assertion that it was vaccine-caused. Otherwise, such an opinion flies completely in the face of well-substantiated decisions by prior special masters, rendered after weighing similar expert testimony against experts who denied vaccines could be causal of ASDs. Petitioner has not made a persuasive showing why Dr. Nikonova's opinion should be viewed in a different light.

[6] Several years ago, more than 5,400 cases were initially filed under short form petition in the Omnibus Autism Proceeding ("OAP"), where thousands of petitioners' claims that certain vaccines caused autism were joined for purposes of efficient resolution. A "Petitioners' Steering Committee" was formed by many attorneys who represent Vaccine Program petitioners, with about 180 attorneys participating. This group chose "test" cases to represent the entire docket, with the understanding that the outcomes in these cases would be applied to cases with similar facts alleging similar theories.

The Petitioners' Steering Committee chose six test cases to present two different theories regarding autism causation. The first theory alleged that the measles portion of the measles, mumps, rubella ("MMR") vaccine precipitated autism, or, in the alternative, that MMR plus thimerosal-containing vaccines caused autism, while the second theory alleged that the mercury contained in thimerosal-containing vaccines could affect an infant's brain, leading to autism.

case for expending the time and money for yet another expert on this topic given the extremely low odds that said expert could offer an opinion based on new science more persuasive than all the expert opinions on the topic that have already been rejected over and over again. *See Hardy v. Secy of Health & Human Servs.*, No. 08-108V, 2015 WL 7732603, at *4–5 (Fed. Cl. Spec. Mstr. Nov. 3, 2015) (referencing eleven autism claims unsuccessfully tried, plus six that were rejected (over the petitioners' objections) without trial).

My decision is also rooted in the facts of this case when considered in light of previously-litigated matters involving causation theories highly similar to the present. *See generally* Mot.; Scheduling Order, dated July 6, 2018 (ECF No. 7). The existing medical record does not support the conclusion that the manifestation of A.R.K.'s autism was atypical for most children with ASDs. *See, e.g., Snyder v. Sec'y of Health & Human Servs.*, No. 01-162V, 2009 WL 332044, at *39, *41–42, *44 (Fed. Cl. Spec. Mstr. Feb. 12, 2009) (discussing manifestation of autism onset, noting loss of skills as typical; "most autism experts accept that skill loss does occur;" mean onset of symptomatology whether or not a child displays regression is between twelve and seventeen months of age). And, based on the available records, none of A.R.K.'s treating physicians have suggested, much less opined, that any vaccines were the cause of A.R.K.'s ASD. Indeed, several records specifically dispute vaccine-causation, or contain no mention of vaccines in a discussion of the potential causes of ASD. *See, e.g.*, Ex. 17 at 23, 266; Ex. 18 at 8. The record otherwise only provides preponderant support for the conclusion that A.R.K. experienced a transient vaccine reaction—not that this reaction precipitated his subsequently-diagnosed ASD.

In opposing Respondent's motion, Petitioner has made no effort to establish that this case is distinguishable from the numerous autism injury claims already litigated in the Program. Instead, she maintains that she has had difficulty in obtaining a complete medical record, and that if she were permitted to do so she would be able to substantiate her contention that A.R.K. did in fact experience an encephalopathy. Opp. at 2. There are two significant problems with this

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The first theory was rejected in three test case decisions, all of which were subsequently affirmed. *See generally Cedillo v. Sec'y of Health & Human Servs.*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *mot. for review denied*, 89 Fed. Cl. 158 (2009), *aff'd*, 617 F.3d 1328 (Fed. Cir. 2010); *Hazlehurst v. Sec'y of Health & Human Servs.*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *mot. for review denied*, 88 Fed. Cl. 473 (2009), *aff'd*, 605 F.3d 1343 (Fed. Cir. 2010); *Snyder v. Sec'y of Health & Human Servs.*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 706 (2009).

The second theory was similarly rejected. *Dwyer v. Sec'y of Health & Human Servs.*, No. 03-1202V, 2010 WL 892250 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *King v. Sec'y of Health & Human Servs.*, No. 03-584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *Mead v. Sec'y of Health & Human Servs.*, No. 03-215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

Ultimately, a total of eleven lengthy decisions by special masters, the judges of the U.S. Court of Federal Claims, and the panels of the U.S. Court of Appeals for the Federal Circuit unanimously rejected petitioners' claims. These decisions found no persuasive evidence that the MMR vaccine or thimerosal-containing vaccines caused autism. The OAP proceedings concluded in 2010.

position, however. First, as discussed above (albeit in summary fashion) there *is* enough record evidence filed to analyze Petitioner's central contention: that A.R.K. experienced a vaccine-induced encephalopathy. The best evidence for such a claim would be derived from the period closest in time to vaccination, not months later, as that would be when the record would either support or reject the conclusion that an encephalopathy occurred.[7] That evidence exists already, and does not preponderantly support Petitioner's contention. As a result, proof of EEGs obtained later on (even two or three months post-vaccination) would not alter my conclusion that Petitioner cannot establish a vaccine-induced encephalopathy in this case.

Second, even if Petitioner could obtain additional relevant medical evidence (at least to support a non-Table claim), her claim still runs up against the numerous cases already decided that persuasively establish that *vaccines do not cause autism*. It is too unlikely that Petitioner could show in this case that the Pentacel vaccine was the cause of A.R.K.'s developmental problems. Petitioner might respond that her theory actually maintains that the vaccine precipitated an encephalopathy, and that *this* was the primary cause of her symptoms (making the vaccine incidental to the ASD). But the Court of Federal Claims has already noted in dealing with similar framing of an autism injury claim that petitioners cannot successfully recast a claim that a vaccine caused autism into an encephalopathy claim. *See, e.g.*, *Cunningham v. Sec'y of Health & Human Servs.*, No. 13–483V, 2017 WL 1174448, at *5 (Fed. Cl. Jan. 25, 2017).

All in all, Petitioner's claim as alleged lacks reasonable basis, and is appropriately dismissed. In so doing, I am aware of Petitioner's likely disappointment, and acknowledge her loving desire (motivated by a reasonable wish to provide good care for A.R.K.) to proceed with the claim. But I must balance such concerns against the unnecessary expenditure of judicial resources that will be occasioned by allowing this matter to go forward. My experience and reasoned judgment in adjudicating vaccine claims involving ASDs strongly informs my conclusion that this claim will not succeed where countless others failed. Because Petitioner has not—despite due opportunity—shown otherwise, I must DISMISS her claim.

[7] The rare cases in which a claimant *succeeded* in establishing a vaccine-caused encephalopathy that produced developmental regression or ASD-like symptoms underscore the importance of immediate evidence of encephalopathy. *See Wright v. Sec'y of Health & Human Servs.*, No. 12-423V, 2015 WL 6665600, at *10 (Fed. Cl. Spec. Mstr. Sept. 21, 2015) (finding that child with ASD-type symptoms experienced a Table encephalopathy; noting that he convulsed and vomited during car ride home after receiving vaccinations (possibly evincing a brief seizure), then became listless, unresponsive, and "basically catatonic" by the following day); *Bast v. Sec'y of Health & Human Servs.*, No. 01-565V, 2012 WL 6858040, at *35–36 (Fed. Cl. Spec. Mstr. Dec. 20, 2012) (discussing case report about Hannah Poling, a successful Vaccine Program claimant who alleged a Table encephalopathy claim for her autism-type symptoms; noting that Hannah developed a high fever, inconsolable crying, irritability, and lethargy, and refusal to walk within forty-eight hours after vaccination), *appeal dismissed sub nom. M.S.B. ex rel. Bast v. Sec'y of Health & Human Servs.*, 579 F. App'x 1001 (Fed. Cir. 2014).

In the absence of a timely-filed motion for review (see Appendix B to the Rules of the Court), the Clerk SHALL ENTER JUDGMENT in accordance with this decision.[8]

s/Brian H. Corcoran
Brian H. Corcoran
Special Master

[8] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.